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October 22, 2007

Gordon H. Mansfield
Deputy Secretary of Veterans Affairs
U.S. Department of Veterans Affairs
810 Vermont Avenue, N.W.
Room 1068
Washington, D.C. 20420

RE: RIN 2900 -AM65 -- "Disclosure of Information to Organ Procurement Organizations"

Dear Deputy Secretary Mansfield:

The Eye Bank Association of America (EBAA) is pleased to provide comments to the Interim Final Rule regulations to implement Section 204 of the Veterans Benefits, Health Care, and Information Technology Act of 2006 (RIN 2900 -AM65, "Disclosure of Information to Organ Procurement Organizations"). The statutory provision and implementing regulations permit the necessary and confidential exchange of medical information for the donation of precious anatomical gifts. The opportunity for donation and honoring one's end-of-life wishes is and has been practiced in civilian health care settings for a number of years. This same opportunity to extend life-giving and life-enhancing gifts will now be extended to our Nation's Veterans and their dependents from Veterans' health care settings. The EBAA commends the Department for its efforts to ensure donation opportunity.

The EBAA is the world's oldest transplantation Association. The 83 eye bank members of the EBAA represent 99% of the entire U.S. eye banking community and provide 97% of all corneal tissue offered for transplant. All eye banks are 501 (c)(3) organizations whose mission is to recover and provide donated human ocular tissue for transplant, and donated human eyes and ocular tissue for research into cures and treatment for diseases of the eye and blindness, and education for physicians.

The Association was the first transplant association to establish Medical Standards for our members. We also have established and administer: 1) a

comprehensive education and certification program for technicians and other eye bank professionals, 2) continuing education programs for ophthalmologists, and 3) an institutionalized program for accreditation for eye banks. EBAA's Medical Standards are specific to banked human eye tissue, scientifically-based and developed to ensure safe transplantation. EBAA's Medical Standards are twice-yearly peer-reviewed and revised when necessary to ensure the practice of state-of-the-art safety procedures. Such standards and procedures are reviewed annually by the American Academy of Ophthalmology.

The EBAA has carefully reviewed the Interim Final Rule, is pleased with its thrust and have found it to include the elements we believe are important for successful donation of anatomical gifts. We strongly support the provisions in the Interim Final Rule, including the definitions and the provisions relating to donation and disclosure. The comments included herein provide an added element of protection with respect to Veterans' Health Administration (VHA) facilities' agreements with eye banks and tissue banks and protected health information. Accordingly, we propose a modification to the rule, some minor refinements, and clarify the discussion in the Preamble. We respectfully urge your consideration of our comments. We believe they will improve the implementation of the statutory provision, provide clarification, and provide an added element of safety for all parties involved in the donation process.

Please note that bold and underlined words, represent EBAA's recommendations to the wording of the Interim Final Rule and/or Preamble. The EBAA does include some recommended language that we have discussed with the American Association of Tissue Banks (AATB). We chose to echo their message and inclusion as we believe it is appropriate to the structure of the Interim Final Rule and practice within the community.

Comments to the Interim Final Rule Language

Recommendation One (see Sections 1.485a (d) and 1.514b (d)):

The EBAA strongly supports the language included in the Interim Final Rule that requires VHA medical centers "to verify annually in January of each calendar year with the Food and Drug Administration (FDA) that an eye bank and tissue bank has complied with the FDA registration requirements of 21 CFR part 1271 before permitting an eye bank or tissue bank to receive protected health information" (see Sections 1.485a (d) and 1.514b (d)). In addition, the EBAA recommends that VHA facilities further verify: 2) whether an eye bank or a tissue bank has an "active status" with the FDA (e.g. is in good standing -- no cease, suspend or limit operations orders), and 3) whether an eye bank is accredited by the Eye Bank Association of America (EBAA) and whether a tissue bank is accredited by the American Association

of Tissue Banks (AATB) for meeting industry medical standards which include standards addressing protection of confidentiality.

Rationale:

The EBAA believes the additional requirements suggested above will afford additional protection for VHA facilities and their respective patient populations. In addition to verifying registration with the FDA, it is important for the VHA facility to further check the status of each eye bank's and tissue bank's registration, whether the registration is active or inactive. If the status is inactive, the VHA facility should not establish an agreement with such eye bank or tissue bank. The reason for the status is not clearly indicated, but could suggest a serious problem, such as the bank was subject to a cease, suspend, or limit operations order. This requirement is relatively easy to verify and should not pose an administrative burden on the facility. The VHA hospital/medical center can also confirm an eye bank's and a tissue bank's registration and status with the FDA via the FDA's "Center for Biologics Evaluation and Research" website. Click on the Human Tissue Program: www.fda.gov/cber/tiss.htm; click on the tab for "Tissue". The website includes a Human Cell and Tissue Establishment Registry with an opportunity for public query. Facilities may also e-mail the agency at: tissuereg@fda.hhs.gov with specific questions relative to cease, suspend, or limit operations orders.

The Eye Bank Association of America (EBAA), and the American Association of Tissue Banks (AATB), are professional Associations for their respective communities. Both Associations inspect and accredit banks for meeting peer reviewed, stringent medical standards; both require adherence to FDA standards. EBAA and AATB standards include confidentiality standards.

The EBAA's standards represent state-of-the-art standards and practices for those who practice eye banking. We inspect eye banks for adherence to our standards and accredit those who pass inspection. Simply stated, non-accredited eye banks do not meet state-of-the-art standards adopted by professionals in the field. VHA facilities should have the benefit of established relationships with banks that meet stringent standards designed by experts in the field. A VHA hospital/medical center can confirm whether an eye bank is accredited by the EBAA. This requirement is relatively easy to verify and should not pose an administrative burden on the facility. A list of accredited facilities can be found on EBAA's website: See the Eye Bank Association of America's website (www.restoresight.org/): tab: "Eye Banks"; tab: "List of Accredited Banks" Additionally, EBAA Medical Standards are posted on our website and will be provided to the Office of the Veterans' Administration National Transplant Program.

Recommended Interim Final Rule Language for both Sections 1.485a (d) and 1.514b (d) :

"to verify annually in January of each calendar year with the Food and Drug Administration (FDA) that an eye bank and tissue bank has complied with the FDA registration requirements of 21 CFR part 1271, **that the registration status is active, and that the eye bank is accredited by the Eye Bank Association of America (EBAA) for eyes/ocular tissue, and that the tissue bank is accredited by the American Association of Tissue Banks (AATB) for tissue.** (see Sections 1.485a (d) and 1.514b (d)).

Corresponding Comments to the Preamble:

Subject: Page 48240 (7th paragraph, last three sentences):

"Consequently, VHA will disclose protected health information to certified OPOs, and to eye banks and tissue banks that have registered with the FDA, and are procuring organs, corneas, and tissues from deceased donors for the purpose of transplantation in compliance with the applicable HHS regulations. VHA will not require these organizations to submit any information or meet any requirements beyond those required by HHS. These regulations provide that VHA medical facilities are to periodically confirm with HHS its approval or certification of each OPO, eye bank or tissue bank that seeks to obtain access to VHA protected health information in order to perform its duties under HHS statutes and regulations. "

EBAA Recommendation: The EBAA recommends that the language in the above noted sentences be changed to correspond with our recommended changes to the Interim Final Rule.

Accordingly, we recommend the following changes to the Preamble:

Page 48240 (7th paragraph, last three sentences):

"Consequently, VHA will disclose protected health information to certified OPOs, and to eye banks and tissue banks that have registered with the FDA **and have an active status,** and are procuring organs, corneas, and tissues from deceased donors for the purpose of transplantation in compliance with the applicable HHS regulations. **As an additional step, the VHA will require facilities to check to see if an eye bank is accredited by the Eye Bank Association of America (EBAA) and if a tissue bank is accredited by the American Association of Tissue Banks (AATB), respective professional organizations, for meeting industry standards.** VHA will not require these organizations to submit any information or meet any requirements beyond those required by HHS **and the verification of accreditation outlined herein.** These regulations provide that VHA medical facilities are to periodically confirm with HHS its approval or certification of each OPO, **and confirmation of registration of each** eye bank or tissue

bank that seeks to obtain access to VHA protected health information in order to perform its duties pursuant to under HHS statutes and regulations. **Further, with respect to eye banks and tissue banks, VHA medical facilities must verify whether an eye bank or tissue bank has an active status with regard to the bank's registration with the Food and Drug Administration, and if the entity is an eye bank, it is accredited by the Eye Bank Association of America (EBAA), and if the entity is a tissue bank, it is accredited by the American Association of Tissue Banks (AATB).**

Note to this Recommendation:

Should the Department choose not to embrace EBAA's and AATB's accreditation requirement in regulatory language, we respectfully seek its consideration in VHA guidance or policy directives to VHA facilities when implementing the requirements of the rule. We believe it will provide an added layer of protection for the facility that documents that an eye or tissue bank is practicing industry standards.

General Comments to the Preamble:

Subject: Page 48239 (Title of Interim Final Rule):

"Disclosure of Information to Organ Procurement Organizations"

EBAA Recommendation: We recommend that the Department change the title of the Interim Final Rule to closely parallel the provisions in the Interim Final Rule and address disclosure as it relates to the three anatomical gifting communities: organ, tissue, and eye. Additionally, a change in title that includes the organ, tissue, and eye communities will correspondingly track Title 42 Code of Federal Regulations, Section 482.45 Medicare and Medicaid Programs, Conditions of Participation for Hospitals, Organ, Tissue, and Eye Procurement. Accordingly, we recommend the following change to the title of the Interim Final Rule:

Page 48239 (Title of Interim Final Regulation):

"Disclosure of Information to Organ, Tissue, and Eye Procurement Organizations"

Subject: Phrase: "national donation program"

Page 48240 (continued paragraph from previous page, last sentence):

"Neither section provided statutory authority for VHA to provide protected health information on deceased patients or patients whose death was

imminent to OPOs, eye banks, and tissue banks for consideration as non-living donors in the national donation program. "
and

Page 48240 (5th paragraph, first sentence): "As discussed above, there are long-established, dynamic, national organ, eye and tissue donation programs in the United States involving non-VHA medical facilities."

EBAA Recommendation: We recommend that the Department not use the phrase, "the national donation program." The phrase suggests that there is one national donation program; this could lead the public to believe that there is one federal clearinghouse that stores all donation information, including protected health information. No "national donation program" for all anatomical gifts exists. At present, programs to promote donation are found at the federal, state and local levels and may be private initiatives, public initiatives, or both. Such programs may be supported with the help of federal, state, local, or private funds. Additionally, federal statutory and regulatory provisions encourage donation by facilitating the donation process, through the elimination of barriers created under law, such as providing for the exchange of necessary health information upon imminent death. At this time, no federal clearinghouse compiles information on donation. In no instance is donation required or mandatory; freedom of choice is preserved and valued. Accordingly, we recommend the following changes to the Preamble:

Page 48240 (continued paragraph from previous page, last sentence): "Neither section provided statutory authority for VHA to provide protected health information on deceased patients or patients whose death was imminent to OPOs, eye banks, and tissue banks for consideration as non-living donors, ~~in the national donation program.~~"
and

Page 48240 (5th paragraph, first sentence): "As discussed above, there are long-established, dynamic, national organ, eye and tissue donation programs in the United States involving non-VHA medical facilities."

Subject: Reference to Medicare and Medicaid Conditions of Participation for Hospitals; Condition of Participation; Organ, Eye, and Tissue Procurement (42 CFR 482.45)

Page 48240 (6th paragraph, second and third sentences): "The regulation requires every Medicare and Medicaid hospital to perform the following concerning organ, eye, and tissue procurement activities: Have an agreement with its designated OPO to report all deaths and imminent deaths to the OPO in a timely manner, collaborate with the OPO to inform families of

potential donors of their donation options, and cooperate with the OPO to maintain potential donors while testing takes place. The regulation also requires hospitals to cooperate with tissue banks and eye banks to ensure that all usable tissues and eyes are obtained."

EBAA Recommendation: The EBAA recommends that the language used in the Preamble carefully track the provisions of Title 42 Code of Federal Regulations, Section 482.45 Medicare and Medicaid Programs, Conditions of Participation for Hospitals, Organ, Tissue and Eye Procurement. This will provide consistent application. We understand and appreciate the need to be brief and to summarize; however, some important points are absent. Accordingly, we recommend that the following changes be incorporated into the Preamble language:

Page 48240 (6th paragraph, second and third sentences): "The regulation requires every Medicare and Medicaid hospital to perform the following concerning organ, eye, and tissue procurement activities: Have an agreement with ~~its a~~ **a designated OPO or third party designated by the OPO, to for the reporting of** all deaths and imminent deaths ~~to the OPO~~ in a timely manner, collaborate with the OPO to inform families of potential donors of their donation options, and cooperate with the OPO, **tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and** to maintain potential donors while testing takes place. The regulation also requires hospitals to **implement written protocols that incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissue as eyes, as may be appropriate** to ensure that all usable tissue and eyes are obtained **from potential donors**.

The EBAA greatly appreciates your review and consideration of our comments. We believe they will enhance the administration of this initiative. The Department has taken an important step in the enactment and practice of a provision which will allow our Nations' Veterans and their dependents to have their final wishes honored. Their wishes will give life, or dramatically enhance the lives, of others. We are proud to be part of this initiative and our banks will serve VHA facilities well. We offer our services in education issues involving donation and giving the gift of sight.

Sincerely,

A large, solid black rectangular redaction box covering the signature of Patricia Aiken-O'Neill.

Patricia Aiken-O'Neill
President and CEO